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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	DEXCOM.008DV1	3546
68851 7590 12/08/2009 KNOBBE, MARTENS, OLSEN & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER NASSER, ROBERT L				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
12/08/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/447,227

Applicant(s)

SHULTS ET AL.

Examiner

ROBERT L. NASSER

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 34, 38, 41, 42, 48, 49, 54-66 and 70-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 33, 34, 38, 41, 42, 48, 49, 54-66 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 8/14/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 34, 38, 41, 42, 48, 49, 56-66, and 70-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan Esch et al 5372133 in view of Picha 5706807 and Bluebaugh Jr. et al 5914026. Claim 34 is rejected in that Hogan-Esch teaches a method of monitoring glucose by implanting a device as shown in figures 2 and 4 into a host, where the device includes a housing 2, a convexly protruding active sensing surface 7, and a membrane 13, 18, and 19 directly in contact with the sensing surface. It does not include the angiogenic layer. However, Picha teaches that it is known to encase an implanted sensor in a layer that is angiogenic or promotes vascularization, to enhance the measurement process, as described in columns 5 and 6. Hence, it would have been obvious to modify Hogan Esch to use such a layer, to improve the measurement process. The combination of Hogan-Esch and Picha has a gap between the sensing region and the membrane. However, Hogan Esch provides no specific reason why there is a gap. Bluebaugh is selected from a myriad references that show a membrane 56, 58 mounted directly on the sensing region 60. As such, it would have been obvious to modify the combination to eliminate the gap, as it is merely the substitution of one known configuration for another. Alternatively, there are a finite number of ways to configure a membrane relative to the sensing surface. One is with a gap and one is without a gap. Hence, it would have been obvious to try the

configuration of Allen. The examiner notes that the combination has a continuously curved membrane in two ways. First, the claim only requires that there be an continuously curved active sensing region and a continuously curved membrane over the sensing region. The active sensing region is only the working electrode 10, which is continuously curved. Therefore, the portion of the membrane over the active electrode is continuously curved. Alternatively, Bluebaugh shows a similar device where the tip has a continuous curve. Hence, it would have been obvious to modify the combination to use such a shape, as it is merely the substitution of one known shape for another. Claim 33 is rejected in that the device of Hogan Esch is wholly implanted. Claim 38 is rejected in that in figure 2, the membrane is "over" the electrode 10. Alternatively, in figure 4, membrane 30 is over a convexly curved membrane 10. Claim 41 is rejected in that the device of Hogan Esch is wholly implanted. Claim 42 is rejected in that there is a transmitter in the device of Hogan Esch. Claims 48 and 49 are rejected in that the sensing membrane contains an enzyme. With respect to claims 56-58, it is the examiner's position that given that the device of the combination has an angiogenic or vascular promoting layer, it would measure glucose accurately for the claimed time periods. With respect to claims 59-61 the examiner notes that it is well known to explant the device when the useful life of the device is over. Claim 62 is rejected in that the layer of the combination would stabilize, as recited. Claim 63 is rejected in that the foam of Picha is a silicone elastomer (see column 3, line 61). Claim 64 is rejected in that the vascularization promotion layer stimulates growth. Claim 65 is rejected in that the sensor is enzymatic. With respect to claims 66 the examiner takes official notice that

non-enzymatic sensors are known glucose sensors. Hence, it would have been obvious to modify Hogan Esch to use a non-enzymatic sensor, as it is merely the substitution of one known equivalent sensor for another. Claims 70-79 are rejected for the reasons given above. Claims 80 and 81 are rejected in that the electrodes can measure enzymatic or non-enzymatic signals. With respect to claims 82-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Allen to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan Esch in view of Picha and Bluebaugh, as applied to claims 33, 34, 38, 41, 42, 48, 49, 56-66, and 70-83 above, further in view of Rhodes WO 92/13271. Rhodes further teaches an alternate membrane assembly that has an electrolytic layer. Hence, it would have been obvious to modify the combination to use such a membrane with an electrolyte layer, as it is merely the substitution of one known equivalent membrane for another.

Applicant's arguments filed 10/1/2009 have been fully considered but they are moot in view of the new grounds of rejection.

The examiner notes that the amendment was insufficient to define over Allen in the sense that the active surface, i.e. the working electrode of Hogan Esch is continuously curved and the membrane at that point would be continuously curved over the active surface. However, Bluebaugh taught eliminating the gap between membrane

and electrode and had a curved shape, so the examiner substituted Bluebaugh for Allen to simplify the rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
12/4/2009

